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(54) Ventilator for continuous positive airway pressure breathing (CPAP).

(57) The present invention discloses both a method of operating CPAP apparatus, and the apparatus itself in which a breathable gas delivery device, or mask (1), is connected to a gas supply pump (14) via a conduit which includes a restriction to gas flow such as a small bore portion (3). A pressure transducer (11) is used to sense the gas pressure at the patient's nose and the transducer output is used to servo-control the pump (14) to maintian the sensed pressure substantially constant.

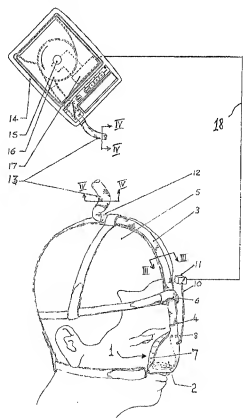

FIG. 1

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The present invention relates to an improved CPAP respiratory apparatus which will increase patient comfort and therefore compliance.

The fundamental disclosure of CPAP is made in the specification of PCT/AU82/00063 published under WO 82/03548 which discloses the supply of air to the nose of the patient at an elevated pressure, the air being supplied through a large bore inlet tube. The elevated pressure at which the air is supplied is approximately 10cm water gauge although pressures in the range of approximately 5-20cm water gauge are encountered. However, this pressure is measured while the patient is not breathing and as the patient inspires and expires the pressure in the patient's mask rises and falls typically by approximately 1-2cm above and below the steady state level. The large bore inlet tube has an unrestricted internal diameter of approximately 20mm and thus does not introduce unacceptably high pressure drops and swings in the gas delivery system during breathing. All commercially available devices have standardised to this size and arrangement.

For the patient, the work of breathing increases in proportion to the size of the pressure swing during the respiration cycle. In particular, the discomfort experienced by the patient also increases in proportion to the increase in mask pressure during breathing out. In order to deliver the patient's breathing air requirements without significant pressure loss in the supply tube, which would create a relatively large pressure swing during the breathing cycle, the delivery tube and inlet to the nose mask were selected to be substantially unrestricted and to have the large bore of approximately 20mm.

However, this arrangement and tubing size are not particularly convenient as far as the comfort of the patient and control of the treatment are concerned. In practice, patients wearing nose masks or equivalent devices including such tubing can turn only from side to side and the freedom of movement of the patient is impaired by the tubing. If the tubing and nose mask could be made smaller, and more acute changes in the direction of air flow tolerated, a much more comfortable and acceptable air delivery system would result. Also if a humidifier and/or a filter could be placed between the pump and the mask, then patient comfort could be increased. Similarly, if a flow measuring device could be so located, control of treatment could be enhanced.

It is the object of the present invention to substantially overcome or ameliorate the above mentioned difficulties by the provision of a CPAP respiratory apparatus which maintains the pressure of air or other breathable gas at the point of immediate access to the patient's respiratory system substantially constant notwithstanding in-line components which introduce appreciable pressure drops.

It is appreciated that increasing the resistance to flow in the supply tube results in an increased pressure drop between the "pump end" and "patient end" of the delivery tube. In order to compensate for this pressure drop between the ends of the delivery tube whilst maintaining flow, the present invention seeks to maintain the air pressure at the "patient end" substantially constant. This is done by sensing the pressure within the nose mask, or equivalent device, itself.

Two known commercially available CPAP respiratory devices involve some pressure or air flow control. One of these is the device sold by RESPIRONICS of the USA under the trade name BIPAP in which the supply pressure can be switched between a lower pressure and a higher pressure in accordance with the patient's respiratory cycle in order to assist the patient's breathing effort. This switching is achieved by sensing air flow through a sensor in the pump of the air supply system. Another commercially available device sold by HEALTHDYNE also of the USA has a control mechanism which controls the pressure at the outlet of the air pump.

Both of these commercially available devices use the standard large bore 20mm inlet tubing which is substantially unrestricted downstream of the pump outlet and will not operate satisfactorily with pressure drop inducing components such as small bore tubing. This is thought (as will be apparent from the experimental data given hereafter) to be due to the large pressure drop which causes large pressure swings in the nose mask as the patient inspires and expires. In particular, because these prior art devices do not attempt to derive the signal to control the operation at the air pump as near to the patient's respiratory system as possible, and downstream of all pressure drop inducing components, there is a problem of time lags and phase shifts as regards the supply of air to and from the patient. It has been experimentally determined by the applicant that by sensing the pressure at the patient's mask and servo-controlling same to be substantially constant, the problems introduced by the pressure drop created in the supply tubing, can be substantially overcome.

In accordance with the first aspect of the present invention there is disclosed a CPAP respiratory apparatus comprising a breathable gas delivery device adapted to deliver breathable gas to the inlet of a patient's respiratory system, a breathable gas supply means having an outlet and arranged to supply breathable gas to said outlet at a pressure above atmospheric pressure, and a flexible conduit having an internal bore and being connected between said outlet and said gas delivery device wherein a pressure transducer is connected to said device to sense the pressure at said respiratory system inlet, and a servo-controller is connected to both said gas supply means and said pressure transducer to adjust the operation of said gas supply means to maintain the pressure at said respiratory system inlet substantially constant.

Preferably, at least that portion of said conduit closest to said nose mask has an internal bore which is

relatively small compared with the remainder of the conduit.

In accordance with a second aspect of the present invention there is disclosed a method of operating a breathable gas supply means of a CPAP respiratory apparatus comprising a breathable gas delivery device adapted to deliver breathable gas to the inlet of a patient's respiratory system and connected by a flexible conduit to an outlet of said gas supply means to receive breathable gas therefrom at a pressure above atmospheric pressure, said method comprising the steps of sensing the pressure supplied to said respiratory system inlet by said gas delivery device, and using the sensed pressure to servo-control said gas supply means to maintain the pressure at said respiratory system inlet substantially constant.

Preferably, at least one pressure drop inducing device is located in the gas supply line between the pump and patient.

Some embodiments of the present invention will now be described with reference to the drawings in which:

Fig. 1 is a schematic perspective view of the nose mask and air supply tube of the CPAP respiratory apparatus of a first embodiment;

Fig. 2 is a partial perspective view of the mask only with its membrane distended;

Figs. 3 and 4 are cross-sectional views along the lines III-III and IV-IV of Fig. 1 respectively;

Fig. 5 is a perspective view of the nose mask, harness and supply conduit of a second embodiment;

Fig. 6 is a view similar to Fig. 5, but of a third embodiment;

Fig. 7 is a view similar to Fig. 5, but of a fourth embodiment;

Fig. 8 is a view similar to Fig. 5, but of a fifth embodiment;

Fig. 9 is an enlarged view of the branched connector of Fig. 8;

Fig. 10 is a front view of the nose mask of Fig. 8;

Fig. 11 is a side elevation of an alternative nose mask;

Fig. 12 is a plan view of the nose mask of Fig. 11;

Fig. 13 is a cross-sectional view taken along the line XIII-XIII of Figs. 5, 6 and 11;

Fig. 14 is a cross-sectional view taken along the line XIV-XIV of Fig. 7;

Fig. 15 is a cross-sectional view taken along the line XV-XV of Figs. 9 and 10; and

Fig. 16 is a view similar to Fig. 1 but illustrating a further embodiment having various different types of pressure drop inducing components.

As seen in Fig. 1 a nose mask 1 is of generally known configuration and is substantially as disclosed in Australian Patent Application No. 77110/91. The mask 1 takes the form of a shell 2 of firm plastics which is shaped to fit over at least the nose region of the patient. A distendable membrane 7 is mounted on the shell 2 and forms a face contacting portion for the mask 1. The shell 2 and membrane 7 together define a chamber which receives the patient's nose. The chamber communicates with an air or other breathable gas supply aperture to which a short length of supply tube 3 is connected. The aperture is preferably provided with a swivel joint 4 so that the supply tube 3 can rotate relative to the remainder of the face mask 1. This prevents the supply tube 3 from becoming inadvertently twisted. The nose mask 1 is retained on the patient 5 by means of conventional straps 6.

In the vicinity of the swivel joint 4 are located a series of apertures 8 through which air or other breathable gas exits to atmosphere as indicated by the arrows in the drawing. Pressure is sensed in the interior chamber of mask 1 by a thin flexible pipe 10 which is connected a pressure transducer 11 which provides an electrical output signal carried on cable 18 to a servo-controller 17 for the pump 14.

The supply tube 3 is of a small bore (typically having an effective internal diameter of 9-15mm) and thus the patient whilst sleeping cannot roll onto an uncomfortable large bore tube. As indicated in Fig. 3 the small bore supply tube 3 in this embodiment has a substantially triangular cross-sectional shape and is flexible. The term "effective internal diameter" means the diameter of a tube of circular internal cross-sectional shape which has the same internal cross-sectional area.

Preferably a swivel joint 12 connects the small bore supply tube 3 to a substantially conventional large bore supply tube 13. The pipe 10 which typically has a very small bore, or the cable 18 can conveniently be connected alongside the supply tubes 3,13. This supports the pipe 10 yet enables the pressure transducer 11 to be located either at, or remote from, the nose mask 1. If desired, the pipe 10 and tube 3 can be combined in a single moulding as indicated by broken lines on Fig. 3. Alternatively, if the pressure transducer 11 is located within, or adjacent to, the mask the electrical outputs signal cable 18 of the transducer can be conveyed to the servo-controller 17 via small pipe 10.

The large bore supply tube 13 is connected to a pump 14 which consists essentially of an electric motor 15 and fan 16. The pump 14 preferably supplies air, however, other breathable gases such as mixtures of air and oxygen can be supplied in known fashion. The term "air" shall be used hereafter for such gases. The electric motor 15 is controlled by a substantially conventional servo-controller 17 which receives as an input, the output from the pressure transducer 11. If desired, the pipe 10 can be sufficiently long to locate the transducer 11 at

the pump 14.

It will be apparent to those skilled in the art that the pressure transducer 11 and servo controller 17 enable the operation of the electric motor 15 to be controlled so as to maintain the air pressure within the nose mask 1 substantially constant. As a result, the electric motor 15 accommodates in its operation the fluctuating internal pressure drop created by both the patient's breathing and the small bore of the supply tube 3. In particular, the supply conduit interconnecting the mask 1 and air pump 14 can now have a small bore (in the range of from 9 to 15mm in internal diameter) over at least part of its length, particularly over that section in the region of the patient's face and head. This represents a decrease in available cross-sectional area of the supply tube 3 from 43.75% to 79.75% respectively.

Because the supply tube 3 has such a reduced bore, the tube is much more flexible and comfortable for the user and can conveniently be fixed to the straps 6 used for holding the nose mask on the patient's face. In particular, it is not generally possible to lie upon the 20mm large bore tubing without feeling discomfort, however, with the relatively small bore supply tube 3 this is possible. As a consequence, the patient's comfort is substantially increased. This increases the patient's compliance, especially after the more pronounced symptoms of sleep apnea have been initially ameliorated. The increased compliance is of particular importance in the long term treatment of the patient.

COMPARATIVE TESTS

The above described apparatus was tested alongside the above mentioned commercially available BIPAP (Respironics) device and TRANQUILITY PLUS device (the trade name of the Healthdyne product).

For the experiment, the large bore supply tube 13 took the form of standard 20mm bore tubing. The length of the small bore supply tube 3 was 17cm. All three units were tested with the same breathing simulator which delivered a substantially sinusoidal air flow having a 500ml tidal volume at 12 cycles/minute. The peak flow during both inspiration and expiration was 50-60 litres per minute.

For each air pump arrangement (BIPAP, TRANQUILITY PLUS and air pump 14) three types of masks were used. The first was a conventional mask with a 20mm constant diameter supply tube (in the case of BIPAP and TRANQUILITY PLUS the mask and tube were as supplied with the equipment). The second mask was the mask 1 with the supply tube 3 being of circular cross-section and of 15mm internal diameter. The third mask was the mask 1 but with 9mm internal diameter for the supply tube 3.

The results for 5 different levels of CPAP pressure (0, 5, 10, 15 and either 17 or 20cm water gauge) are set out in Table 1. the figures given are air pressures in cm of water gauge with P_{stat} being the average or static pressure within the mask whilst ΔP_{tot} is the combined pressure swing during the inspiration/expiration cycle of the breathing simulator.

It can be seen that the combined pressure swing ΔP_{tot} increases significantly with decreasing tubing diameter with the HEALTHDYNE and BIPAP units, while the servo-controlled unit 14 maintains pressure in the mask 1 generally to better than 1 cm total swing for all sizes of tubing. It follows therefore that an improved result allowing the use of the more comfortable small bore tubing, has been achieved.

A second embodiment is illustrated in Fig. 5 where like parts are indicated by a designator increased in magnitude by 20. Thus, the mask 21 of the second embodiment is a face mask and includes a pressure transducer 11 located within the mask 21 as indicated by broken lines in Fig. 5. The transducer 11 is located within the mask 21 and between the patient's nose and the apertures 8. A substantially similar arrangement of straps 26 retains the nose mask 21 in position. As indicated in Fig. 13, the cross-sectional shape of the small bore inlet tube 23 is circular. Again, the small bore inlet tube 23 is connected to the conventional large bore inlet tube 13 by means of a substantially conventional swivel joint 12.

A third embodiment is illustrated in Fig. 6 in which the nose mask 21 and small bore inlet tube 23 are substantially as in Fig. 5. However, a flow orifice 111 (preferably of the type disclosed in U.S. patent No. 4,006,635 [Billette]) only is located in the mask 21 and is connected by two small tubes 210 to a flow transducer 110. The tubes 210 are located one upstream and one downstream of the flow orifice 111. As before, the pressure transducer 11 is connected to the mask 21 via the tube 10. In addition, a cap 29 with straps 36 is provided for the patient in order to secure the small bore inlet tube 23.

A fourth embodiment is illustrated in Fig. 7 in which like parts have their designator increased in magnitude by 40 relevant to the embodiment of Fig. 1. It will be seen that the configuration of the nose mask 41 is changed so as to provide a swivel joint 49 which is sufficiently large to accommodate the pressure transducer 11 which is again located downstream of the apertures 48. The configuration of the straps 46 is also different and provides an alternative securing arrangement.

Figs. 8-10 illustrate a fifth embodiment in which a nose mask 51 is supplied by means of a split or dual inlet tubes 53 each of which is supplied from a branch swivel connector 54 illustrated in more detail in Fig. 9.

The connector 54 is located to the rear of the patient's head and the nose mask 51 is secured in position by means of a forehead strap 56.

As seen in Fig. 9, the branch connector 54 includes an elbow 61 which swivels as indicated by the arrow in Fig. 9, relative to a Y-piece 62. The inlet tubes 53 are sealed directly to the Y-piece 62.

Fig. 10 illustrates further detail of the nose mask 51 and, in particular, illustrates the cavity 64 which receives the patient's nose. The flow orifice 111 is located within the inlet to the cavity 64 as are the exit apertures 68. It will be seen that the inlet tubes 53 extend across each cheek of the patient and alongside the nose mask 51. As seen in Fig. 15, the inlet tubes 53 preferably have a flat configuration and are provided with a plurality of internal ribs 69 which prevent the inlet tube 53 being crushed between the pillow and the patient's head.

Turning now to Figs. 11 and 12, a still further embodiment of the nose mask 71 is illustrated. The nose mask 71 has a substantially rigid outer shell 72 which has an inlet 73 of substantially circular cross-section which includes exit apertures 78 and is sufficiently large to accommodate the pressure transducer 11 as illustrated (or the flow transducer 110 - not illustrated). Sealingly connected to the outer shell 72 is a soft membrane 77 which is shown in Figs. 11 and 12 in its distended position and has a nose receiving aperture 79. Once the nose of the patient is inserted into the aperture 79, the membrane 77 then conforms itself to the surface of the patient's skin thereby providing an effective seal.

As indicated in Fig. 14, if desired the inlet tube 3, and equivalents, can be provided with two internal passageways 80 which can be used either to transmit pressure from the region adjacent the patient's nose or to locate the electric cable(s) from transducer(s).

With the above described distendable mask, the deformable membrane has hitherto stretched and compressed with changes in the mask pressure. This oscillation is somewhat disturbing to the patient and is substantially eliminated in accordance with the above since the servo-controller 17 maintains the mask pressure substantially constant.

Furthermore, most of the noise escaping from a CPAP device comes either from the air inlet or air outlet. This can be reduced by placing baffles in the air inlet and/or the air outlet, but with the prior art devices this is at the expense of increasing the pressure drop and pressure swings in the mask during inspiration and expiration.

In accordance with the above described arrangements, this additional baffling can be added and the pressure swings that would otherwise result can be compensated for by servo-controlling the pressure in the mask. Since mask comfort and noise level are the two most important determinants of patient comfort and compliance, this represents a substantial advantage.

Like the small bore tube 3,23 and the connector 54, such baffles represent pressure drop inducing components. As indicated in Fig. 16, such components can take the form of baffles 301, sharp bends 302, a filter 303, a high pressure drop air outlet diffuser 304 having a diverting tube to direct flow away from a sleeping partner, a flow orifice 111 and a humidifier 306 such as a hydroscopic condensing humidifier made by ICOR AB of Sweden. The pressure drop introduced by any or all of these "accessories" can be accommodated so as to maintain the pressure at the patient's nose substantially constant .

If desired, the transducers 11,110 can be located at or near the mask as illustrated and connected by cables 18 to the control apparatus 17. Alternatively, the tubes 10,210 can be sufficiently long to enable the transducers 11,110 to be located adjacent the pump 14. This arrangement has the advantage that no electric cables are located near the patient.

In addition, if the positions of the flow orifice 111 and humidifier 306 shown in Fig. 16 are reversed, then a combined sensing arrangement is possible. In this arrangement the flow orifice 111 is connected to the flow transducer 110 as before via two tubes 210. The downstream one of the tubes 210 is branched to provide the tube 10 for the pressure transducer 11.

The foregoing describes only some embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto without departing from the scope of the present invention.

For example, although a nose mask is described and illustrated in detail, a full face mask or nasal prongs can also be used.

TABLE I

BIPAP UNIT

	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot
Conv. Mask			5.0	1.00	10.0	1.20	15.0	1.40	20.00	2.40
New Mask 15				1.20		1.30		1.40		2.00
New Mask 9				2.20		2.70		3.80		5.40

HEALTHDYNE TRANQUILITY PLUS

	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot
Conv. Mask	0.0	0.70	5.0	0.85	10.0	1.10	15.0	1.35	17.00	1.40
New Mask 15		1.20		1.40		1.80		2.10		2.20
New Mask 9		2.20		3.20		4.20		4.80		5.10

SERVO-CONTROLLED UNIT 14

	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot	Pstat	ΔPtot
Conv. Mask	0.0	0.40	5.0	0.35	10.0	0.45	15.0	0.60	20.00	0.90
New Mask 15		0.75		0.48		0.52		0.65		0.95
New Mask 9		0.90		1.05		0.65		0.75		0.90

Claims

1. A CPAP respiratory apparatus comprising a breathable gas delivery device adapted to deliver breathable gas to the inlet of a patient's respiratory system, a breathable gas supply means having an outlet and arranged to supply breathable gas to said outlet at a pressure above atmospheric pressure, and a flexible conduit having an internal bore and being connected between said outlet and said gas delivery device wherein a pressure transducer is connected to said device to sense the pressure at said respiratory system inlet, and a servo-controller is connected to both said gas supply means and said pressure transducer to adjust the operation of said gas supply means to maintain the pressure at said respiratory system inlet substantially constant.

2. Apparatus as claimed in claim 1, wherein said gas delivery device comprises a nose mask.

3. Apparatus as claimed in claim 1 or 2, wherein said flexible conduit includes pressure drop inducing means.

4. Apparatus as claimed in claim 3, wherein said pressure drop inducing means comprises at least that portion of said conduit closest to said gas delivery device which has an internal bore which is relatively small compared with the remainder of said conduit.

5. Apparatus as claimed in claim 4, wherein said small bore portion is joined to the remainder of said conduit by a swivel joint.

6. Apparatus as claimed in claim 4 or 5, wherein said small bore portion has a flattened non-circular profile.

7. Apparatus as claimed in claim 4, 5 or 6, wherein said small bore portion is arranged to pass between the eyes of said patient.

8. Apparatus as claimed in claim 6, wherein said small bore portion is bifurcated and includes two parts which each extend from behind the head of said patient past the corresponding cheek to said gas delivery device.

9. Apparatus as claimed in any one of claims 4-8, wherein said small bore portion includes a pressure port and/or a transducer cable.

10. Apparatus as claimed in claim 3, wherein said pressure drop inducing means is selected from the class consisting of a bend in said conduit, a swivel joint in said conduit, a pressure transducer, a humidifier, a filter, baffle means, a flow measuring orifice and an adapter to connect portions of said conduit of different effective internal diameters.

11. A method of operating a breathable gas supply means of a CPAP respiratory apparatus comprising a breathable gas delivery device adapted to deliver breathable gas to the inlet of a patient's respiratory system and connected by a flexible conduit to an outlet of said gas supply means to receive breathable gas therefrom at a pressure above atmospheric pressure, said method comprising the steps of sensing the pressure supplied to said respiratory system inlet by said gas delivery device, and using the sensed pressure to servo-control said gas supply means to maintain the pressure at said respiratory system inlet substantially constant.

12. A method as claimed in claim 11, wherein said gas delivery device comprises a nose mask having a nose receiving cavity, and said sensed pressure is the pressure within said cavity.

13. A method as claimed in claim 11 or 12, including the step of locating a pressure drop inducing means in said conduit.

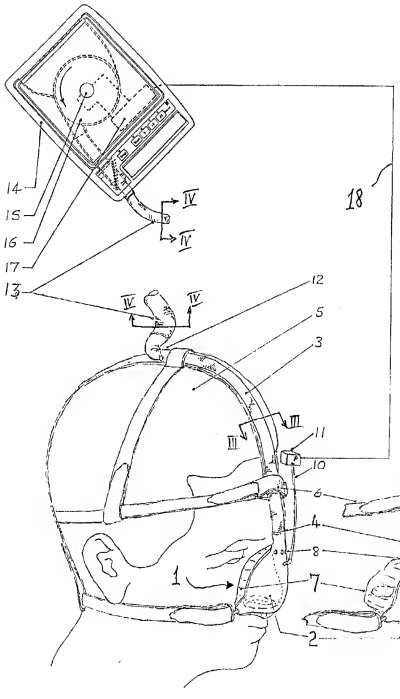


FIG. 1

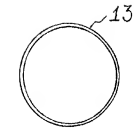


FIG. 4

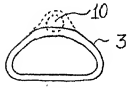


FIG. 3

FIG. 2

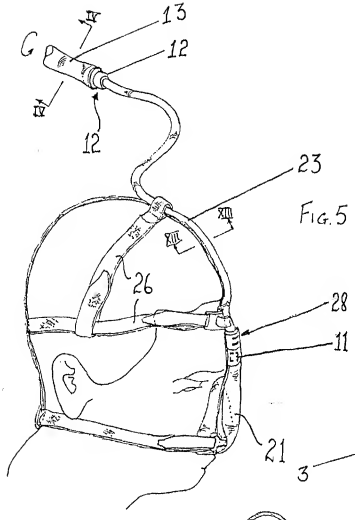


FIG. 5

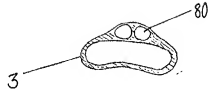
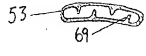


FIG. 14

FIG. 13

FIG. 15



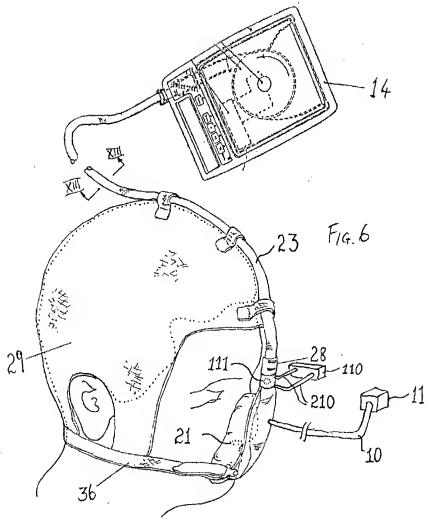


FIG. 6

FIG. 10

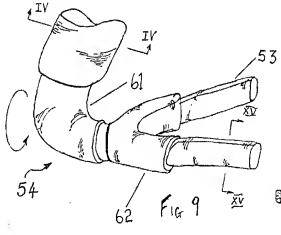
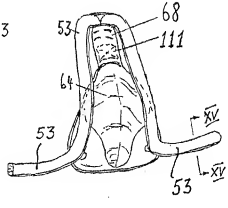


FIG 9



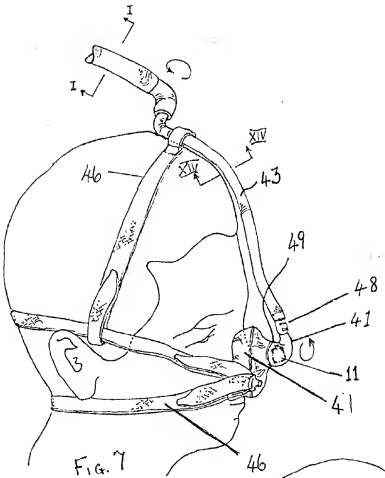


FIG.7

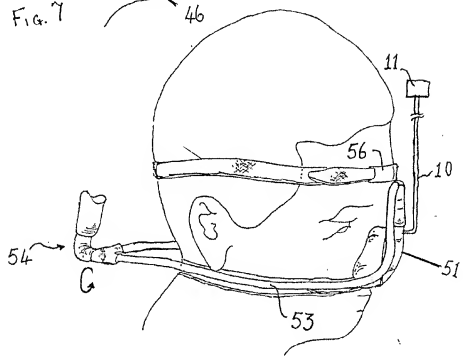


FIG.8

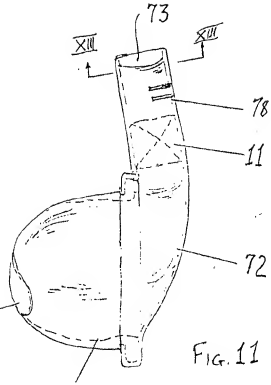


FIG. 11

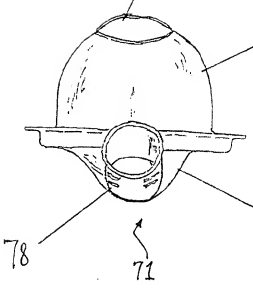


FIG. 12

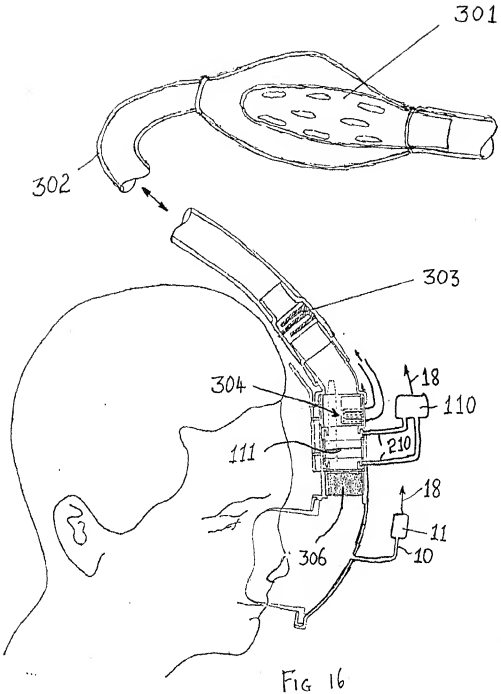


FIG 16